



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US97/11792</p> <p>(22) International Filing Date: 3 July 1997 (03.07.97)</p> <p>(30) Priority Data:</p> <table border="0"> <tr> <td>60/021,420</td> <td>9 July 1996 (09.07.96)</td> <td>US</td> </tr> <tr> <td>9617898.3</td> <td>28 August 1996 (28.08.96)</td> <td>GB</td> </tr> <tr> <td>60/029,351</td> <td>31 October 1996 (31.10.96)</td> <td>US</td> </tr> </table> <p>(71) Applicant (for all designated States except US): MERCK &amp; CO., INC. [US/US]; 126 East Lincoln Avenue, Rahway, NJ 07065 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): MITCHEL, Yale, B. [US/US]; 126 East Lincoln Avenue, Rahway, NJ 07065 (US). TOBERT, Jonathan, A. [US/US]; 126 East Lincoln Avenue, Rahway, NJ 07065 (US).</p> <p>(74) Common Representative: MERCK &amp; CO., INC.; 126 East Lincoln Avenue, Rahway, NJ 07065 (US).</p>	60/021,420	9 July 1996 (09.07.96)	US	9617898.3	28 August 1996 (28.08.96)	GB	60/029,351	31 October 1996 (31.10.96)	US	<p>(81) Designated States: AL, AM, AU, AZ, BA, BB, BG, BR, BY, CA, CN, CU, CZ, EE, GE, HU, IL, IS, JP, KG, KR, KZ, LC, LK, LR, LT, LV, MD, MG, MK, MN, MX, NO, NZ, PL, RO, RU, SG, SI, SK, SL, TJ, TM, TR, TT, UA, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report: 12 February 1998 (12.02.98)</p>
60/021,420	9 July 1996 (09.07.96)	US								
9617898.3	28 August 1996 (28.08.96)	GB								
60/029,351	31 October 1996 (31.10.96)	US								
<p>(54) Title: METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA</p> <p>(57) Abstract</p> <p>Homozygous familial hypercholesterolemia can be treated in patients suffering with this condition by administering a therapeutically effective amount of simvastatin. Dosages above 40 mg/day, and more particularly at or above 80 mg/day, were found to effectively reduce the LDL cholesterol levels in these patients.</p>										

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INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/11792

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC(6) :A61K 31/365  
US CL :514/460  
According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**  
Minimum documentation searched (classification system followed by classification symbols)  
U.S. : 514/460

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
CHEMICAL ABSTRACTS

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S). Lancet. November 1994, Vol. 19:344, pages 1383-9 (1994) (Abstract).	1-9
A	US, 5,393,893 A (KUBELA et al.) 28 February 1995, see entire document.	1-9
A	US, 4,997,849 A (PETUCH et al.) 05 March 1991, see entire document.	1-9

Further documents are listed in the continuation of Box C.  See patent family annex.

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| *A* document defining the general state of the art which is not considered to be of particular relevance   | *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |
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| *P* document published prior to the international filing date but later than the priority date claimed   |  |

Date of the actual completion of the international search 03 NOVEMBER 1997	Date of mailing of the international search report 15 DEC 1997
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13245748

Basic Patent (No, Kind, Date): GB 9617898 A0 19961009 <No. of Patents: 007>

Patent Family:

Patent No	Kind	Date	Applic No	Kind	Date	
AU 9736672	A1	19980202	AU 9736672	A	19970703	
AU 9742289	A1	19980202	AU 9742289	A	19970703	
AU 9743261	A1	19980202	AU 9743261	A	19970703	
GB 9617898	A0	19961009	GB 9617898	A	19960828	(BASIC)
WO 9801116	A1	19980115	WO 97US12426	A	19970703	
WO 9801100	A2	19980115	WO 97US11792	A	19970703	
WO 9801119	A2	19980115	WO 97US10867	A	19970703	

Priority Data (No, Kind, Date):

GB 9617898 A 19960828  
US 21420 P 19960709  
US 29351 P 19961031  
WO 97US12426 W 19970703  
WO 97US11792 W 19970703

WO 97US10867 W 19970703

PATENT FAMILY:

AUSTRALIA (AU)

Patent (No,Kind,Date): AU 9736672 A1 19980202  
THERAPY FOR COMBINED HYPERLIPIDEMIA (English)  
Patent Assignee: MERCK & CO INC  
Author (Inventor): MITCHEL YALE B; MELINO MICHAEL R  
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
19960709; US 29351 P 19961031; WO 97US12426 W 19970703  
Applic (No,Kind,Date): AU 9736672 A 19970703  
IPC: \* A61K-009/20  
CA Abstract No: \* 128(09)097715J; 128(09)097716K; 128(11)132435S  
Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191  
Language of Document: English

Patent (No,Kind,Date): AU 9742289 A1 19980202  
METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (English)  
Patent Assignee: MERCK & CO INC  
Author (Inventor): MITCHEL YALE B; TOBERT JONATHAN A  
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
19960709; US 29351 P 19961031; WO 97US11792 W 19970703  
Applic (No,Kind,Date): AU 9742289 A 19970703  
IPC: \* A61K-031/00  
CA Abstract No: \* 128(09)097715J; 128(09)097716K; 128(11)132435S  
Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191  
Language of Document: English

Patent (No,Kind,Date): AU 9743261 A1 19980202  
PHARMACEUTICAL COMPOSITIONS (English)  
Patent Assignee: MERCK & CO INC  
Author (Inventor): MITCHEL YALE B; TOBERT JONATHAN A  
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
19960709; US 29351 P 19961031; WO 97US10867 W 19970703  
Applic (No,Kind,Date): AU 9743261 A 19970703  
IPC: \* A61K-031/00  
CA Abstract No: \* 128(09)097715J; 128(09)097716K; 128(11)132435S  
Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191  
Language of Document: English

GREAT BRITAIN (GB)

Patent (No,Kind,Date): GB 9617898 A0 19961009  
METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (English)  
Patent Assignee: MERCK & CO INC  
Priority (No,Kind,Date): GB 9617898 A 19960828  
Applic (No,Kind,Date): GB 9617898 A 19960828  
Language of Document: English

WORLD INTELLECTUAL PROPERTY ORGANIZATION, PCT (WO)

Patent (No,Kind,Date): WO 9801116 A1 19980115  
THERAPY FOR COMBINED HYPERLIPIDEMIA (English)  
Patent Assignee: MERCK & CO INC (US); MITCHEL YALE B (US); MELINO  
MICHAEL R (US)  
Author (Inventor): MITCHEL YALE B (US); MELINO MICHAEL R (US)  
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
19960709; US 29351 P 19961031  
Applic (No,Kind,Date): WO 97US12426 A 19970703  
Designated States: (National) AL; AM; AU; AZ; BB; BG; BR; BY; CA; CN;  
CZ; EE; GE; HU; IL; IS; JP; KG; KR; KZ; LK; LR; LT; LV; MD; MG; MK;

MN; MX; NO; NZ; PL; RO; RU; SG; SI; SK; SL; TJ; TM; TR; TT; UA; US;  
UZ; VN; YU; AM; AZ; BY; KG; KZ; MD; RU; TJ; TM (Regional) GH; KE;  
LS; MW; SD; SZ; UG; ZW; AT; BE; CH; DE; DK; ES; FI; FR; GB; GR; IE;  
IT; LU; MC; NL; PT; SE; BF; BJ; CF; CG; CI; CM; GA; GN; ML; MR; NE;  
SN; TD; TG

Filing Details: WO 100000 With international search report

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128(09)097716K

Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191; C  
98-110207

Language of Document: English

Patent (No,Kind,Date): WO 9801100 A2 19980115

METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (English)

Patent Assignee: MERCK & CO INC (US); MITCHEL YALE B (US); TOBERT  
JONATHAN A (US)

Author (Inventor): MITCHEL YALE B (US); TOBERT JONATHAN A (US)

Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
19960709; US 29351 P 19961031

Applic (No,Kind,Date): WO 97US11792 A 19970703

Designated States: (National) AL; AM; AU; AZ; BA; BB; BG; BR; BY; CA;  
CN; CU; CZ; EE; GE; HU; IL; IS; JP; KG; KR; KZ; LC; LK; LR; LT; LV;  
MD; MG; MK; MN; MX; NO; NZ; PL; RO; RU; SG; SI; SK; SL; TJ; TM; TR;  
TT; UA; US; UZ; VN; YU; AM; AZ; BY; KG; KZ; MD; RU; TJ; TM  
(Regional) GH; KE; LS; MW; SD; SZ; UG; ZW; AT; BE; CH; DE; DK; ES; FI  
; FR; GB; GR; IE; IT; LU; MC; NL; PT; SE; BF; BJ; CF; CG; CI; CM; GA;  
GN; ML; MR; NE; SN; TD; TG

Filing Details: WO 130000 With international search report; Before  
expiration of time limit for amending the claims and to be  
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IPC: \* A61K

CA Abstract No: \* 128(09)097715J; 128(09)097716K; 128(11)132435S;  
128(09)097715J

Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191; C  
98-110203

Language of Document: English

Patent (No,Kind,Date): WO 9801119 A2 19980115

PHARMACEUTICAL COMPOSITIONS (English)

Patent Assignee: MERCK & CO INC (US); MITCHEL YALE B (US); TOBERT  
JONATHAN A (US)

Author (Inventor): MITCHEL YALE B (US); TOBERT JONATHAN A (US)

Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
19960709; US 29351 P 19961031

Applic (No,Kind,Date): WO 97US10867 A 19970703

Designated States: (National) AL; AM; AU; AZ; BB; BG; BR; BY; CA; CN;  
CZ; EE; GE; HU; IL; IS; JP; KG; KR; KZ; LK; LR; LT; LV; MD; MG; MK;  
MN; MX; NO; NZ; PL; RO; RU; SG; SI; SK; SL; TJ; TM; TR; TT; UA; US;  
UZ; VN; YU; AM; AZ; BY; KG; KZ; MD; RU; TJ; TM (Regional) GH; KE;  
LS; MW; SD; SZ; UG; ZW; AT; BE; CH; DE; DK; ES; FI; FR; GB; GR; IE;  
IT; LU; MC; NL; PT; SE; BF; BJ; CF; CG; CI; CM; GA; GN; ML; MR; NE;  
SN; TD; TG

Filing Details: WO 300000 Without international search report and to  
be republished upon receipt of that report

IPC: \* A61K-031/00

CA Abstract No: \* 128(09)097715J; 128(09)097716K; 128(11)132435S;  
128(11)132435S

Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191; C

98-145191  
Language of Document: English

WORLD INTELLECTUAL PROPERTY ORGANIZATION, PCT (WO)

Legal Status (No, Type, Date, Code, Text):

WO 9801100	P	19960709	WO AA	PRIORITY CLAIMED
		US 21420	P	19960709
WO 9801100	P	19960828	WO AA	PRIORITY (PATENT)
		GB 9617898	A	19960828
WO 9801100	P	19961031	WO AA	PRIORITY CLAIMED
		US 29351	P	19961031
WO 9801100	P	19970703	WO AE	APPLICATION DATA (APPL. DATA)
		WO 97US11792	A	19970703
WO 9801100	P	19980115	WO AK	DESIGNATED STATES CITED IN A PUBLISHED APPLICATION WITHOUT SEARCH REPORT (DESIGNATED STATES CITED IN A PUBLISHED APPL. WITHOUT SEARCH REPORT)
		AL AM AU AZ BA BB BG BR BY CA CN CU CZ EE GE HU IL IS JP KG KR KZ LC LK LR LT LV MD MG MK MN MX NO NZ PL RO RU SG SI SK SL TJ TM TR TT UA US UZ VN YU AM AZ BY KG KZ MD RU TJ TM		
WO 9801100	P	19980115	WO AL	DESIGNATED COUNTRIES FOR REGIONAL PATENTS CITED IN A PUBLISHED APPLICATION WITHOUT SEARCH REPORT (DESIGNATED COUNTRIES FOR REGIONAL PATENTS CITED IN A PUBLISHED APPL. WITHOUT SEARCH REPORT)
		GH KE LS MW SD SZ UG ZW AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN ML MR NE SN TD TG		
WO 9801100	P	19980115	WO A2	PUBLICATION OF THE INTERNATIONAL APPLICATION WITHOUT THE INTERNATIONAL SEARCH REPORT (PUB. OF THE INTERNATIONAL APPL. WITHOUT THE INTERNATIONAL SEARCH REPORT)
WO 9801100	P	19980326	WO DFPE	REQUEST FOR PRELIMINARY EXAMINATION FILED PRIOR TO EXPIRATION OF 19TH MONTH FROM PRIORITY DATE
WO 9801100	P	19980520	WO 121	EP: PCT APP. ART. 158 (1) (EP: PCT ANM. ART. 158 (1))
WO 9801100	P	19990604	WO NENP	<u>NON-ENTRY INTO THE NATIONAL PHASE IN:</u>
		<u>JP</u>	1998505308	
WO 9801100	P	20000109	WO NENP	<u>NON-ENTRY INTO THE NATIONAL PHASE IN:</u>
		<u>CA</u>		
WO 9801100	P	20000209	WO 122	<u>EP: PCT APP. NOT ENT. EUROP. PHASE (EP: PCT ANM. NICHT IN EUROP. PHASE EING.)</u>
WO 9801116	P	19960709	WO AA	PRIORITY CLAIMED
		US 21420	P	19960709
WO 9801116	P	19960828	WO AA	PRIORITY (PATENT)
		GB 9617898	A	19960828
WO 9801116	P	19961031	WO AA	PRIORITY CLAIMED
		US 29351	P	19961031
WO 9801116	P	19970703	WO AE	APPLICATION DATA (APPL. DATA)

DATA)  
WO 97US12426 A 19970703

WO 9801116 P 19980115 WO AK DESIGNATED STATES CITED IN A  
PUBLISHED APPLICATION WITH SEARCH REPORT  
(DESIGNATED STATES CITED IN A PUBLISHED APPL.  
WITH SEARCH REPORT)  
AL AM AU AZ BB BG BR BY CA CN CZ EE GE HU IL  
IS JP KG KR KZ LK LR LT LV MD MG MK MN MX NO  
NZ PL RO RU SG SI SK SL TJ TM TR TT UA US UZ  
VN YU AM AZ BY KG KZ MD RU TJ TM

WO 9801116 P 19980115 WO AL DESIGNATED COUNTRIES FOR  
REGIONAL PATENTS CITED IN A PUBLISHED  
APPLICATION WITH SEARCH REPORT (DESIGNATED  
COUNTRIES FOR REGIONAL PATENTS CITED IN A  
PUBLISHED APPL. WITH SEARCH REPORT)  
GH KE LS MW SD SZ UG ZW AT BE CH DE DK ES FI  
FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI  
CM GA GN ML MR NE SN TD TG

WO 9801116 P 19980115 WO A1 PUBLICATION OF THE  
INTERNATIONAL APPLICATION WITH THE  
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WO 9801116 P 19980212 WO DFPE REQUEST FOR PRELIMINARY  
EXAMINATION FILED PRIOR TO EXPIRATION OF 19TH  
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WO 9801116 P 19980506 WO 121 EP: PCT APP. ART. 158 (1)  
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WO 9801116 P 19990604 WO NENP NON-ENTRY INTO THE NATIONAL  
PHASE IN:  
JP 1998505391

WO 9801116 P 20000109 WO NENP NON-ENTRY INTO THE NATIONAL  
PHASE IN:  
CA

WO 9801116 P 20000112 WO 122 EP: PCT APP. NOT ENT. EUROP.  
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EING.)

WO 9801119 P 19960709 WO AA PRIORITY CLAIMED  
US 21420 P 19960709

WO 9801119 P 19960828 WO AA PRIORITY (PATENT)  
GB 9617898 A 19960828

WO 9801119 P 19961031 WO AA PRIORITY CLAIMED  
US 29351 P 19961031

WO 9801119 P 19970703 WO AE APPLICATION DATA (APPL.  
DATA)  
WO 97US10867 A 19970703

WO 9801119 P 19980115 WO AK DESIGNATED STATES CITED IN A  
PUBLISHED APPLICATION WITHOUT SEARCH REPORT  
(DESIGNATED STATES CITED IN A PUBLISHED APPL.  
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AL AM AU AZ BB BG BR BY CA CN CZ EE GE HU IL  
IS JP KG KR KZ LK LR LT LV MD MG MK MN MX NO  
NZ PL RO RU SG SI SK SL TJ TM TR TT UA US UZ  
VN YU AM AZ BY KG KZ MD RU TJ TM

WO 9801119 P 19980115 WO AL DESIGNATED COUNTRIES FOR  
REGIONAL PATENTS CITED IN A PUBLISHED  
APPLICATION WITHOUT SEARCH REPORT



(DESIGNATED COUNTRIES FOR REGIONAL PATENTS  
CITED IN A PUBLISHED APPL. WITHOUT SEARCH  
REPORT)

GH KE LS MW SD SZ UG ZW AT BE CH DE DK ES FI  
FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI  
CM GA GN ML MR NE SN TD TG

WO 9801119 P 19980115 WO A2 PUBLICATION OF THE  
INTERNATIONAL APPLICATION WITHOUT THE  
INTERNATIONAL SEARCH REPORT (PUB. OF THE  
INTERNATIONAL APPL. WITHOUT THE INTERNATIONAL  
SEARCH REPORT)

WO 9801119 P 19980312 WO DFPE REQUEST FOR PRELIMINARY  
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WO 9801119 P 19980506 WO 121 EP: PCT APP. ART. 158 (1)  
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WO 9801119 P 19990604 WO NENP NON-ENTRY INTO THE NATIONAL  
PHASE IN:  
JP 1998505217

WO 9801119 P 19991110 WO 122 ~~EP: PCT APP. NOT ENT. EUROP.~~  
PHASE (EP: PCT ANM. NICHT IN EUROP. PHASE  
EING.)

WO 9801119 P 20000109 WO NENP NON-ENTRY INTO THE NATIONAL  
PHASE IN:  
CA